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# Evaluation of an enhanced cleaning and storage method for in-office disinfection of hydrogel contact lenses

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## Abstract

Even though a trial contact lens has been cleaned prior to storage, there is little guarantee that the lens storage environment is sterile (except in the case of autoclaving the lens within the storage vial). The underside of the cap is often an overlooked potential source of contamination to the system. This study evaluated the effectivity of Bausch & Lomb ReNu Multi-Purpose Solution as an in-office storage solution using an enhanced cleaning method, as well as the utility of inverting the lens vial during the disinfecting period. The results show that inversion of the vial assists in assuring a more growth free environment, yet proper cleaning of the lens and the vial stopper is vital to obtain maximum effectiveness with this in-office contact lens storage system.



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Contact lenses, disinfection, in-office storage, contamination, cleaning, ReNu Multi-Purpose Solution

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# *EVALUATION OF AN ENHANCED CLEANING AND STORAGE METHOD FOR IN-OFFICE DISINFECTION OF HYDROGEL CONTACT LENSES*

by

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## Biographies

**Gordon E. Dramen** received his B.S. in General Science from Oregon State University, Corvallis, OR in 1989. He is a candidate for an O.D. degree at Pacific University College of Optometry in May of 1992. He has been a member of Beta Sigma Kappa, Phi Kappa Phi, and Phi Theta Kappa during his college career. He received the first place award in the "Optometry School Award Program" contest sponsored by Allergan Inc.. His future plans include practicing optometry in Oregon.

**Gayle D. Dramen** received her B.S. in Medical Technology from St. Cloud State University, St. Cloud, MN in 1988. She is a candidate for an O.D. degree at Pacific University College of Optometry in May of 1992. She has also received recognition for first place in the "Optometry School Award Program" contest. Her future plans include practicing optometry in Oregon.

**Cristina M. Schnider, O.D., F.A.A.O.** is an assistant professor of optometry at Pacific University College of Optometry in Forest Grove, Oregon. Other past achievements include: serving 3.5 years as manager of Rigid Lens Clinical Studies at the Cornea and Contact Lens Research Unit in Sydney, Australia, and appointed assistant clinical professor at the State University of New York College of Optometry following graduation from Pacific University College of Optometry in 1982. Currently, she is contributing editor of "Contact Lens Spectrum" and is an advisory panel member of the RGP Lens Institute.

**Abstract:**

Even though a trial contact lens has been cleaned prior to storage, there is little guarantee that the lens storage environment is sterile (except in the case of autoclaving the lens within the storage vial). The underside of the cap is often an overlooked potential source of contamination to the system. This study evaluated the effectivity of Bausch & Lomb ReNu Multi-Purpose Solution as an in-office storage solution using an enhanced cleaning method, as well as the utility of inverting the lens vial during the disinfecting period. The results show that inversion of the vial assists in assuring a more growth free environment, yet proper cleaning of the lens and the vial stopper is vital to obtain maximum effectiveness with this in-office contact lens storage system.

**Key words:**

Contact lenses, disinfection, in-office storage, contamination, cleaning, ReNu Multi-Purpose Solution.

**Introduction:**

The disinfection of diagnostic/trial hydrogel lenses is of utmost importance to the contact lens practitioner to prevent cross-contamination between patients. Eyecare providers have potentiated the spread of viral keratitis (e.g. EKC)[1] through improper disinfection of Goldmann tonometer probes and possibly diagnostic lenses. Moreover, it has been documented that bacterial contamination of hydrogel lenses can lead to ocular complications as serious as total loss of sight due to ulcerative bacterial keratitis[2-6].

To fully understand reports concerning the antimicrobial effectiveness of any agent or solution, however, it is important to understand the terminology associated with this area of research: *sterilization*, *disinfection*, and *preservative*. *Sterilization* is the process, either physical or chemical, that destroys any viable form of the organism, including even highly resistant bacterial endospores. In contrast, *disinfection* is a procedure that may not inactivate spores, tubercle bacilli, and certain viruses, but will reduce the level of microbial contamination. Disinfection is therefore generally less lethal than sterilization. Presently, the Food and Drug Administration (FDA) requires that inanimate objects such as contact lenses undergo the process of disinfection, but not sterilization. The term *preservative* refers to the ingredients in a solution that prevent microorganism multiplication. The same antimicrobial ingredient(s) may be used as both the preservatives and the disinfecting agents in contact lens

solutions, differing only in their concentration or the exposure to the ingredient(s)[7].

Currently there are a limited number of options for in-office disinfection of hydrogel lenses approved by the FDA. The heat disinfection method works well for low water content lenses, but is unacceptable for repeated routine disinfection of the high water content lenses, causing a degradation of the lens polymer[8]. Many offices have resorted to one-step chemical disinfection systems because of their ease of application. ReNu Multi-Purpose Solution, a product of Bausch & Lomb, is such a one-step disinfection system approved by the FDA for in-office storage[9]. A drawback to one-step chemical disinfection systems is that a longer disinfection period must be implemented compared to the heat disinfection method. Usually a 4 hour to an overnight soak is required to achieve antimicrobial effectiveness comparable to heat [10].

ReNu Multi-Purpose Solution is a storage medium that utilizes Dymed (polyaminopropylbiguanide 0.00005%) and edetate disodium as the bacteriocidal disinfection agents, which, according to laboratory testing are stated as being noncytotoxic, nonirritating and nonsensitizing[11]. At the present time, ReNu Multi-Purpose Solution is limited by the FDA to a maximum contact lens soaking/storage period of only 7 consecutive days; whereas, OPTI-FREE a product of Alcon Laboratories, Inc. is FDA approved for a maximum contact lens storage period of 90 days. On the other hand, Weisbarth recommends that lenses in storage be cleaned and disinfected at regular weekly

intervals and that the entire cleaning process be repeated 24 hours before lens insertion[10].

Studies have shown that patient's contact lens cases (cap and well) provide an ideal environment in which bacteria thrive[12-15]. The vials used to store diagnostic hydrogel lenses in-office provide the same potential environment for bacteria to propagate. The vial cap is likely to become contaminated through repeated opening of the vial. It is almost impossible to remove the cap without touching its underside with a thumb or finger. The cap must be set aside so that both hands can be used to extract the contact lens from the vial, becoming further contaminated with air-borne bacteria or with bacteria found on the counter top. Moreover, if the vial is stored in the traditional upright fashion, the cap underbelly never makes contact with the disinfection solution, becoming a potential source of contamination to the storage system (see Figure 1).


**Figure 1.** Bausch & Lomb ReNu Multi-Purpose Solution with vials stored in traditional upright orientation.

This study was designed to determine whether caps and/or lenses were a source of contamination to a in-office storage system, and whether the cleaning or the storage method would alter the extent of bacterial growth after a 15 day storage period in the disinfecting solution.

**Materials and Methods:**

The four experiments required 99 new factory sealed vials containing Bausch & Lomb Medalist (polymacon, HEMA, 38.6% water) lenses of various powers. The rubber vial caps and the lenses were contaminated with bacteria from three different econiches that the hydrogel system could potentially come in contact with under normal contact lens handling.

These challenge bacteria represent the most likely sources of contamination to a hydrogel system, as well as those organisms that are associated with debilitating visual loss. The econiches that the bacteria were derived from included:

1. normal flora found on the skin (S)
2. normal flora found inside the mouth (M)
3. *Pseudomonas aeruginosa* (ATCC 27853)

The normal flora found on the skin of a contact lens patient or provider can contaminate the lens-care system through repeated

handling. It has also been documented that some patients use their saliva to rewet or "clean" a lens that has dislodged from the eye when no other sterile wetting agent is available; thereby introducing normal flora from the mouth into the lens-care system. *Pseudomonas aeruginosa* was chosen because it represents a bacterial organism that is responsible for the majority of all contact lens associated corneal ulcers and can cause perforation to a compromised cornea within as little as 24 hours[1].

The lenses and caps to be contaminated were exposed to normal skin flora by rubbing them across the hands and forearm of the experimenter. They were exposed to normal mouth flora by licking the lens and the cap underbelly by the experimenter. *Pseudomonas aeruginosa* (ATCC 27853) was introduced to the cap and lens via a swab from a blood agar plate culture of *P. aeruginosa* donated from a local medical lab. In each case, the lenses and caps were allowed to sit for approximately two minutes to insure that the contaminants had a chance to adhere before further manipulation.

Of the 78 contaminated lenses and caps, 39 of the lenses were placed directly into vials that were filled two-thirds of the way full with ReNu Multi-Purpose Solution, their respective rubber caps replaced, and sealed with a metal top. The remaining 39 contaminated lenses and caps were subjected to two different cleaning regimens; a minimal and a thorough cleaning (see Table 1). The 21 controls were factory-sealed vials that remained unopened until the contents were swabbed and plated.

The minimal cleaning regimen of the cap underbelly and lens consisted of digitally rubbing them with the ReNu Multi-Purpose Solution for approximately 5 seconds, then rinsing them off with ReNu before sealing the vial that was filled two-thirds of the way with ReNu. This method best approximates the type of in-office cleaning that a hurried technician or a typical noncompliant contact lens wearer might perform.

The thorough cleaning regimen was the same as that used for the minimal cleaning regimen except the cap underbelly and lens were digitally rubbed for 10 seconds instead of only 5 seconds. This more thorough cleaning regimen would probably only apply to the most fastidious lens-care provider. In fact, Bausch & Lomb unrealistically recommends in their package insert that each side of the lens should be digitally cleaned for 20 seconds with a few drops of ReNu Multi-Purpose Solution for a total of 40 seconds per lens. On the other hand, the insert does mention that good lens care practice includes emptying the lens case, rinsing it out with ReNu, and allowing it to air dry[16].

Vials were further manipulated by storing some of them upside-down for various lengths of time. The vials were subjected to three different inversion time lengths during the 15 day storage period:

1. some not at all.
2. some for only 15 hours.
3. the others for 15 days (see Figures 1, 2 and Table 1).

The 15 day storage time was selected to determine the effect of exceeding the FDA recommendation of 7 days. The 15 hour inversion time best approximates the time lenses would be stored if they were cleaned at the end of the day and returned to stock the following morning.


**Figure 2**. Bausch & Lomb ReNu Multi-Purpose Solution with vials inverted for overnight storage.

**Table 1**: Experimental Protocol Summary

| Exp. | N | Contaminants | Cleaning Method | Inversion Time | Storage Time |
|---|---|---|---|---|---|
| 1a | 14 | (3) Controls<br>(4) Pseudomonas<br>(4) Mouth (M)<br>(3) Skin (S) | None | 0 | 15 Days |
| 1b | 11 | (3) Controls<br>(3) Pseudomonas<br>(3) M<br>(2) S | None | 15 Days | 15 Days |
| 2a | 11 | (3) Controls<br>(2) Pseudomonas<br>(3) M<br>(3) S | Minimally Cleaned | 0 | 15 Days |
| 2b | 13 | (2) Controls<br>(3) Pseudomonas<br>(3) M<br>(5) S | Minimally Cleaned | 15 Days | 15 Days |
| 3a | 12 | (2) Controls<br>(3) Pseudomonas<br>(4) M<br>(3) S | None | 0 | 15 Days |
| 3b | 13 | (3) Controls<br>(2) Pseudomonas<br>(5) M<br>(3) S | None | 15 hours | 15 Days |
| 4a | 12 | (2) Controls<br>(3) Pseudomonas<br>(4) M<br>(3) S | Thorough Cleaning | 0 | 15 Days |
| 4b | 13 | (3) Controls<br>(3) Pseudomonas<br>(4) M<br>(3) S | Thorough Cleaning | 15 hours | 15 Days |

At the end of the 15 day storage period, the cap underside and solution from each vial was individually sampled using a separate sterile cotton swab for each. The samples were streaked onto corresponding numbered sterile trypticase soy blood agar plates, utilizing standard microbiological techniques. The inference was

made that if the soaking solution was contaminated then it was probable that the lens was contaminated also; therefore, the lenses themselves were not swabbed.

The plates were incubated at 37 degrees Celsius for 48 hours. After the incubation period, the plates were examined by another experimenter in a masked fashion so that she was not aware of how the vials had been contaminated, cleaned, nor stored. The bacterial growth on the plates was quantified using the scale: no growth (N/G), rare (less than 6 colonies), 1+, 2+, 3+, and 4+ growth (see figure 3).

**Figure 3.** Plates illustrating rare growth, and 1+, 2+, 3+ and 4+ growth used for grading.

Data for all 4 experiments were combined for Kruskal Wallis analysis to determine the effects of lens cleaning regimen, vial inversion time, and the method of contamination on the amount of growth observed.

**Results:**

Table 2 contains summaries of the amount of bacterial growth observed from the cap underside and the solution from each vial from the four different experiments.

**Table 2**: Experiment Results

Experiment #1: uncleaned

| A. Right side-up for 15 days | | | B. Inverted for 15 days | | |
|---|---|---|---|---|---|
| vial | cap | solution | vial | cap | solution |
| (3) Cntrl | N/G | N/G | (3) Cntrl | N/G | N/G |
| (3) Pseudo | 4+ | 3+ | (3) Pseudo | 2+ | 1+ |
| (1) Pseudo | 4+ | 1+ | | | |
| (1) M | N/G | N/G | (2) M | N/G | N/G |
| (1) M | 1+ | rare | (1) M | rare | N/G |
| (1) M | 1+ | N/G | | | |
| (1) M | 3+ | N/G | | | |
| (1) S | N/G | N/G | (1) S | rare | rare |
| (1) S | rare | N/G | (1) S | 1+ | rare |
| (1) S | 3+ | 3+ | | | |

Legend: (Cntrl) Control; (Pseudo) *P. aeruginosa*; (M) Mouth flora; (S) Skin flora.

Experiment #2: minimally cleaned

| A. Stored right side-up for 15 days | | | B. Stored inverted for 15 days | | |
|---|---|---|---|---|---|
| vial | cap | solution | vial | cap | solution |
| (3) Cntrl | N/G | N/G | (2) Cntrl | N/G | N/G |
| (2) Pseudo | rare | N/G | (1) Pseudo | N/G | N/G |
| | | | (1) Pseudo | rare | N/G |
| | | | (1) Pseudo | N/G | rare |
| (2) M | N/G | N/G | (3) M | N/G | N/G |
| (1) M | rare | rare | | | |
| (1) S | N/G | N/G | (4) S | N/G | N/G |
| (1) S | rare | rare | (1) S | rare | N/G |
| (1) S | 1+ | N/G | | | |

Experiment #3: uncleaned

| A. Right side-up for 15 days | | | B. Inverted 15 hours then right side-up for rest of the15 days | | |
|---|---|---|---|---|---|
| vial | cap | solution | vial | cap | solution |
| (2) Cntrl | N/G | N/G | (3) Cntrl | N/G | N/G |
| (1) Pseudo | 3+ | N/G | (1) Pseudo | N/G | N/G |
| (1) Pseudo | 2+ | rare | (1) Pseudo | rare | rare |
| (1) Pseudo | 4+ | 1+ | | | |
| (1) M | 2+ | 1+ | (3) M | N/G | N/G |
| (1) M | 2+ | 2+ | (1) M | rare | rare |
| (1) M | 3+ | 1+ | (1) M | 1+ | rare |
| (1) M | 4+ | rare | | | |
| (1) S | 2+ | 2+ | (3) S | N/G | N/G |
| (1) S | 4+ | 2+ | | | |
| (1) S | 4+ | 3+ | | | |

Legend: (Cntrl) Control; (Pseudo) *P. aeruginosa*; (M) Mouth flora; (S) Skin flora.

Experiment #4: thoroughly cleaned

| A. Right side-up for 15 days | | | B. Inverted 15 hours then right side-up for rest of the15 days | | |
|---|---|---|---|---|---|
| vial | cap | solution | vial | cap | solution |
| (2) Cntrl | N/G | N/G | (3) Cntrl | N/G | N/G |
| (3) Pseudo | N/G | N/G | (3) Pseudo | N/G | N/G |
| (3) M | N/G | N/G | (4) M | N/G | N/G |
| (1) M | rare | N/G | | | |
| (2) S | N/G | N/G | (3) S | N/G | N/G |
| (1) S | rare | N/G | | | |

Significantly less growth was seen:

1. with the control lenses (versus contaminated lenses).
2. when cleaning had occurred (versus the uncleaned).
3. when the vial was inverted (compared to stored upright).

There was no significant difference between:

1. the minimal and thorough cleaning's.
2. the 15 hour versus 15 day inversion times.

The statistical analyses are summarized in Tables 3 and 4.

**Table 3.** Statistical Analyses: Kruskal-Wallis test
DF = 2, 3 groups, 99 cases

| Variable | Source | H value (corrected for ties) | Mean rank | p value |
|---|---|---|---|---|
| Clean Method | Cap | 18.812 | | 0.0001 |
| None | | | **-0.407** | |
| Minimal | | | -0.143 | |
| Thorough | | | -0.12 | |
| | Solution | 23.48 | | 0.0001 |
| None | | | **-0.411** | |
| Minimal | | | -0.136 | |
| Thorough | | | -0.123 | |
| Inversion Time | Cap | 23.776 | | 0.0001 |
| None | | | **-0.398** | |
| 15 Hours | | | -0.131 | |
| 15 Days | | | -0.141 | |
| | Solution | 13.181 | | 0.0014 |
| None | | | **-0.373** | |
| 15 Hours | | | -0.146 | |
| 15 Days | | | -0.151 | |
| Contaminant | Cap | 13.421 | | 0.0038 |
| Pseudomonas | | | -0.164 | |
| Mouth | | | **-0.234** | |
| Skin | | | -0.184 | |
| Control | | | **-0.088** | |
| | Solution | 9.706 | | 0.0212 |
| Pseudomonas | | | -0.147 | |
| Mouth | | | **-0.242** | |
| Skin | | | -0.182 | |
| Control | | | **-0.099** | |

**Table 4.** Statistical Analyses: Kruskal-Wallis test
DF = 7, 8 groups, 99 cases

| Variable | Source | H Value (Corrected for Ties) | Mean rank | p value |
|---|---|---|---|---|
| Experiment | Cap | 50.978 | | 0.0001 |
| 1a | | | **-0.13** | |
| 1b | | | -0.074 | |
| 2a | | | -0.075 | |
| 2b | | | -0.067 | |
| 3a | | | **-0.13** | |
| 3b | | | -0.076 | |
| 4a | | | -0.063 | |
| 4b | | | -0.057 | |
| Experiment | Solution | 45.851 | | 0.0001 |
| 1a | | | **-0.124** | |
| 1b | | | -0.081 | |
| 2a | | | -0.066 | |
| 2b | | | -0.070 | |
| 3a | | | **-0.124** | |
| 3b | | | -0.081 | |
| 4a | | | -0.059 | |
| 4b | | | -0.064 | |

**DISCUSSION:**

Contamination of the vial cap and contact lens is almost impossible to avoid during repeated handling and fitting as is the case with diagnostic lenses used in-office. We have shown that the cap underbelly will harbor bacterial growth when contaminated. This commonly overlooked fact can potentially lead to cross-contamination between patients in a contact lens-provider setting.

Bacterial growth on the cap is retarded if the diagnostic lens vial is inverted allowing the disinfection solution to come in contact with the cap. Unfortunately, the mere inversion of the vial alone does not

insure a growth-free environment of the vial contents. Moreover, our results indicate that there is not a significant difference between inverting for 15 hours (overnight) versus inverting the vial for 15 days. Almost all inverted vials that were not subjected to a cleaning regimen had some quantifiable bacterial growth on either the cap or in the solution for both time lengths.

The issue of digital cleaning is also a key one, as surveys have shown that patients do not comply with the cleaning regimen recommended by the manufacturer, and it can be assumed that doctors and their staff will probably do no better[17, 18]. This is an unfortunate fact because the FDA only grants approval of the effectivity and safety of a storage solution when the instructions for cleaning and disinfecting are followed explicitly[9].

However, this study shows that enhanced bacteriocidal efficacy can be achieved when digital cleaning of the lens AND the rubber cap is added to inversion of the vials as part of the disinfection regimen. As one would expect, thorough cleaning regimen yielded a more growth-free environment than the minimal cleaning technique when combined with inverting the vial, although the difference was not statistically significant. Digitally cleaning a lens for a total of 40 seconds with ReNu according to manufacturer recommendations is an unrealistic expectation for most patients and lens-care providers alike, but the 10 second cleaning regimen in our study did yield favorable results, with or without inversion.

In conclusion, we feel that the regimen for an in-office disinfection and storage of diagnostic lenses should include a thorough digital cleaning of both the cap and the contact lens prior to storage. We also recommend inverting the vial for 15 hours (overnight) before returning the lenses to the fitting set. The inverted vials in the morning also alert the staff to the fact that they have undergone proper disinfection and are safe to store for reuse.

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